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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,871	04/13/2004	Robert J. Deleys	BJS-2551-141	3673

23117 7590 10/06/2008

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EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,871	DELEYS ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55,59,60,62 and 68-93* is/are pending in the application.

4a) Of the above claim(s) *74-76 and 90-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55, 59, 60, 62, 68-73 and 77-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/13/04 and 8/18/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/920,286.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 2, 2008 has been entered.

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 74-76 and 90-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 20, 2007.

Claims 55, 59, 60, 62 and 68-89 are examined on the merits.

Examiner's Note

Applicants have requested verification regarding the updated bibliographic data sheet indexed on May 2, 2007 (dated April 13, 2007). The present examiner edited this document and the initials "BPB" are also present next the information added. Applicants have also requested that an updated bibliographic data sheet containing the verification of foreign priority claim also

be included. The examiner has completed this request, and also directs applicants to the first page of the Office actions of May 2, 2007 and February 5, 2008 in which the foreign priority claim was acknowledged.

Response to Arguments

Applicant's arguments filed June 9, 2008 have been fully considered but they are not persuasive. See responses below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(New Rejection) Claims 55, 59, 60, 62 and 68-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 55, 71-73 and 77-84 claim various amino acid residue regions of a HCV polyprotein. For example, claim 55 recites, "...(a) a first molecule...amino acids 1-20, 7-26, 8-18, 13-32, 37-56, 49-68, 61-80 and 73-92 of an HCV polyprotein...", however, it is unclear which portion of such a polyprotein amino acids 1-20, for example, is directed towards since HCV polyproteins are general longer than 3000 amino acid residues. It is therefore suggested that applicants amend these claims in which amino acid domains are claimed (i.e., claims 55, 71-73 and 77-84) to refer to an amino acid sequence representing a specific HCV polyprotein SEQ ID NO:, such as SEQ ID NO: 23. Claims 59, 60, 62, 68-70 and 85-89 are rejected since they depend from claims 55, 71-73 and 77-84.

Claim 55 recites, "A combination of separate molecules, comprising (a) a first molecule...(b) a second molecule...(c) a third molecule...and said combination including at least

one molecule selected from the group consisting of SEQ ID NO: 1, …" (see page 2 of response), however, it is unclear if the claimed 'composition of separate molecules' comprises (a), (b), (c) and at least one further molecule, or if the 'composition of separate molecules' comprises (a), (b) and (c) or at least one molecule as recited on the last two lines of page 2 of applicant's response. If applicants meant that the former is the intended invention, it is suggested that line 18 of claim 55 recite, "…said combination further includes at least one molecule selected from…".

Claim 55 recites, "…A combination of separate molecules…", however, it is unclear how a product can be a combination and yet be separate. It is therefore suggested that claim 55 be amended to recite, "A combination of heterologous molecules…", or "A combination of distinct molecules…"

Claim 71 recites, "…(a) a first molecule…group consisting of amino acids 1-20, 7-26, 8-18, 13-32, 37-56, 49-68, 61-80 and 73-92 of an HCV polyprotein, SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, and SEQ ID NO: 8; and

(b) a second molecule…group consisting of amino acids 1688-1707, 1694-1713, 1706-1725, 1712-1731, 1718-1737), 1724-1743 and 1730-1749 of an HCV polyprotein, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14 and SEQ ID NO: 15, and

(c) a third molecule…group consisting of amino acids 2263-2282, 2275-2294, 2287-2306, 2299-2318, and 2311-2330 of an HCV polyprotein, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, and SEQ ID NO: 20,

wherein said molecules of (a), (b) and (c) are each separate molecules from one another, wherein said molecules of (a), (b) and (c) are each different from one another and wherein said molecules are selected from the group consisting of peptides and polypeptides, and wherein at least one of said first, second and third molecules is selected from the group consisting of:

a first molecule comprising HCV polyprotein amino acids only from amino acids 1-92 of an HCV polyprotein or only from amino acids 1-92 of SEQ ID NO: 23;

a second molecule comprising HCV polyprotein amino acids only from amino acids 1688-1749 of an HCV polyprotein or only from amino acids 1688-1749 of SEQ ID NO: 23; and

a third molecule comprising HCV polyprotein amino acids only from amino acids 2263-2330 of an HCV polyprotein or only from amino acids 2263-2330 of SEQ ID NO: 23…", however, it is unclear how the 20 amino acid fragments of (a), (b) and (c) can also be larger fragments of 92, 61 and 67 amino acids in length, respectively.

Claims 72 and 73 are also indefinite since they require that while their independent claim (55) states that the first, second and third amino acid sequences are:

"…(a) a first molecule…group consisting of amino acids 1-20, 7-26, 8-18, 13-32, 37-56, 49-68, 61-80 and 73-92 of an HCV polyprotein, SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, and SEQ ID NO: 8; and

(b) a second molecule…group consisting of amino acids 1688-1707, 1694-1713, 1706-1725, 1712-1731, 1718-1737), 1724-1743 and 1730-1749 of an HCV polyprotein, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14 and SEQ ID NO: 15, and

(c) a third molecule…group consisting of amino acids 2263-2282, 2275-2294, 2287-2306, 2299-2318, and 2311-2330 of an HCV polyprotein, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, and SEQ ID NO: 20,…", claims 72 and 73 require the (a) is amino acids 1-92 of HCV polyprotein, (b) is amino acids 1688-1749 of HCV polyprotein, and/or (c) is amino acids 2263-2330 of HCV polyprotein. Are molecules (a), (b), and/or (c) the smaller fragments as recited in claim 55 or these later claimed larger fragments of claims 72 and 73?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55, 59, 60, 62 and 68-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 55 recites, "…consisting at least 5 to less than 20 amino acids…" for several different amino acid sequences; claims 71-73 recite, "…from amino acids 1-92…from amino acids 1688-1749…2263-2330…"; and claims 77-80 recite, "…other than amino acids 1-6…" however, there is no support in the specification for molecules based on such amino acid

regions of any protein as recited in claims 71-73 and 77-80, nor fragments other than at least 5, 6, 8 or 12 amino acids in length, in the specification. Claim 78 is rejected since it depends from claim 71.

Double Patenting

(Prior Rejection Maintained) Claims 55, 59, 60, 62, 68-73 and 77-89 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

claims 1-7, 12, 19-22, 27, 32, 33 and 38 of U.S. Patent No. 6,007,982;

claims 1-6, 13-15, 22, 23, 26, 39 and 40 of U.S. Patent No. 5,910,404;

claims 1-6, 13-24 and 26 of U.S. Patent No. 6,872,520 B2;

claims 1-5, 7, 12 and 21-24 of U.S. Patent No. 5,922,532;

claims 1-3, 5-7, 9-11, 13-15, 17-24, 27 and 28 of U.S. Patent No. 6,287,761 B1; and

claims 1, 3, 4, 6, 7 and 9-12 of U.S. Patent No. 6,576,417 B2.

Applicants have requested that these rejections be held in abeyance until allowable subject matter has been indicated. These rejections have been maintained for reasons of record.

Claim Rejections - 35 USC § 102

(New Rejection Necessitated by Amendments) Claims 55, 59, 60, 62, 68-73 and 77-89 are rejected under 35 U.S.C. 102(e) as anticipated by Houghton et al. (US 5,350,671).

The claimed invention is drawn to a combination of three distinct peptides of HCV each consisting of a specific amino acid sequence. The first peptide comprises at least 5 amino acids from SEQ ID NOs: 1-8 or from amino acid positions 1-20, 7-26, 8-18, 13-32, 37-56, 49-68, 61-80 or 73-92 of any HCV polyprotein. The second peptide comprises at least 5 amino acids from SEQ ID NOs: 9-15 or from amino acid positions 1688-1707, 1694-1713, 1706-1725, 1712-1731,

1718-1737, 1724-1743 or 1730-1749 of any HCV polyprotein. The third peptide comprises at least 5 amino acids from SEQ ID NOs: 16-20 or the amino acid positions 2263-2282, 2275-2294, 2287-2306, 2299-2318 or 2311-2330 of any HCV polyprotein. The peptides are produced by either recombinant expression or by chemical synthesis, and one or more of the peptides comprises a fusion protein, which can be synthetic. The combination of peptides is also part of a kit for detecting HCV infection in a human body component by screening for reactive antibodies for the peptides of the claimed invention that are coating an immunoassay plate. The combination also includes at least one additional protein selected from: SEQ ID NO:s 1-20; or a peptide consisting of at least 5 to less than 20 amino acids in the regions consisting amino acids 7-26, 13-32, 49-68, 1688-1707, 1694-1713, 1706-1725, 1712-1731, 1724-1743, 2287-2306, 2299-2318, 2311-2330 (all of any HCV polyprotein), of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO:s 9-12, SEQ ID NO: 14, and SEQ ID NO:s 18-20; or a peptide consisting of at least 5 to less than 12 amino acids in the region consisting of amino acids 1718-1737, 1730-1749 (all of any HCV polyprotein), of SEQ ID NO: 13 or SEQ ID NO: 15; or a peptide consisting of 5, 6, 8, 12 or 20 amino acids of amino acids 37-56, 61-80, or 73-92 of any HCV polyprotein; or a peptide consisting of amino acids 37-56, 61-80 or 73-92 of any HCV polyprotein. Therefore, given the broadest reasonable interpretation, the claimed invention is a peptide combination of at least 4 HCV polyprotein fragments that are different from each other in which at least 5 amino acids of each fragment must either be identical to any 5 amino acid residues from 4 sequences of SEQ ID NO:s 1-20 or any 5 amino acid residues of any HCV polyprotein (which includes non-full length polyproteins).

Houghton et al. teach the development of a peptide library of HCV. The peptides of the library could be as short as 5 amino acids. These peptides can be employed in an assay for detecting HCV specific antibodies in biological fluids and can be a fusion protein between the HCV peptide and Super Oxide Dismutase (SOD). One example of such an assay is an ELISA, in which the peptides can be added to the wells of a plate and the reactive antibodies can be detected. Houghton et al. further teach that "An antigenic region of a polypeptide is generally relatively small--typically 8 to 10 amino acids or less in length. Fragments of as few as 5 amino acids may characterize an antigenic region. These segments may correspond to regions of HCV antigen…polypeptides comprising truncated HCV amino acid sequences encoding at least one viral epitope are useful immunological reagents. For example, polypeptides comprising such truncated sequences can be used as reagents in an immunoassay. These polypeptides also are candidate subunit antigens in compositions for antiserum production or vaccines. While these truncated sequences can be produced by various known treatments of native viral protein, it is generally preferred to make synthetic or recombinant polypeptides comprising an HCV sequence. Polypeptides comprising these truncated HCV sequences can be made up entirely of HCV sequences (one or more epitopes, either contiguous or noncontiguous), or HCV sequences and heterologous sequences in a fusion protein. Useful heterologous sequences include sequences that provide for secretion from a recombinant host, enhance the immunological reactivity of the HCV epitope(s), or facilitate the coupling of the polypeptide to an immunoassay support or a vaccine carrier…The size of polypeptides comprising the truncated HCV sequences can vary widely, the minimum size being a sequence of sufficient size to provide an HCV epitope, while the maximum size is not critical. For convenience, the maximum size usually is

not substantially greater than that required to provide the desired HCV epitopes and function(s) of the heterologous sequence, if any. Typically, the truncated HCV amino acid sequence will range from about 5 to about 100 amino acids in length. More typically, however, the HCV sequence will be a maximum of about 50 amino acids in length, preferably a maximum of about 30 amino acids. It is usually desirable to select HCV sequences of at least about 10, 12 or 15 amino acids, up to a maximum of about 20 or 25 amino acids." *See column 27, lines 3-6 and 59-68 and column 28, lines 1-10 and lines 15-29*. Some suggested amino acid regions that can be tested are provided below (*it is noted that Houghton et al. doesn't teach the specific fragment of residues 2275-2294*).

AA-AA of Houghton et al.	Claimed Amino acid positions
AA1-AA25	1-20, 7-26
AA5-AA20	8-18
AA1-AA50	13-32
AA1-AA84	37-56
AA45-AA65	49-68
AA65-AA75	61-80
AA80-AA92	73-92
AA1690-AA1720	1688-1707, 1694-1713, 1706-1725
AA1694-AA1735	1712-1731, 1718-1737
AA1720-AA1745	1724-1743, 1730-1749
AA2265-AA2280	2263-2282
AA2250-AA2330	2275-2294
AA2290-AA2310	2287-2306, 2299-2318
AA2310-AA2330	2311-2330

Response to arguments:

Applicants argue that Houghton et al. do not describe the specific sequences required in claim 71 (i.e., at least one of a sequence of amino acids 1-92 of an HCV polyprotein, a sequence

of amino acids 1-92 of SEQ ID NO: 23, a sequence of amino acids 1688-1749 of an HCV polyprotein, a sequence of amino acids 1688-1749 of SEQ ID NO: 23, a sequence of amino acids 2263-2330 of an HCV polyprotein, and a sequence of amino acids 2263-2330 of SEQ ID NO: 23). Applicants also state that the cited patent (Houghton et al.) was considered by the Patent Office in each of the previously granted related parent applications which claim at least one product required by independent claim 55 and claims dependent therefrom. As noted above, independent claim 71 requires molecules not described by the cited patent. Entry of the present Amendment and withdrawal of the Section 102 rejection are requested.

In response, the newly added limitations of claims 55 and 71 do not have support in the specification (see 35 U.S.C. 112 1st paragraph rejection above). Furthermore, Houghton et al. teach that truncated HCV polyproteins used in immunoassays can range from 5 to about 100 amino acids in length, therefore, the limitations of claims 71 with regard to a protein comprising the residues 1-92, 1688-1749 and 2263-2330 of an HCV polyprotein are taught by Houghton et al. (see column 28, lines 67 and 68 through column 29 and Figure 66). With regard to the previous parent applications having already overcome Houghton et al., applicants are reminded that each patent application is examined on its merits independently from previously filed or co-pending applications with common inventorship and/or assignment. Furthermore, the scope of the instant invention is broader as compared to that of the patented inventions cited below, since the instant invention claims amino acids sequences comprising any HCV polyprotein fragment or from specific sequence identifiers (SEQ ID NO).

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
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/BENJAMIN P BLUMEL/
Examiner
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